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| EXAMINER | | | | |
| NGUYEN, TUAN VAN | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/065,279

Applicant(s)

LEUNG ET AL.

Examiner

TUAN V. NGUYEN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 22, 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58, 60 and 63-140 is/are pending in the application.
- 4a) Of the above claim(s) 37-57 and 63-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36, 58, 60, and 102-140 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 and 16 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-58, 60 and 63-140 are pending in this present application. In previous Office action claims 1-36, 58, 60 and 102-140 were examined and rejected and claims 37-57 and 63-101 were previously withdrawn due to restriction requirement.

Response to Amendment

2. Claims 1, 10, 19, 28, 37, 44, 51, 58 and 60 have been amended and no new matter is added.
3. Applicant's arguments filed on 5/27/09 with respect to the Buncke fails to disclose new limitation in independent claims 1, 10, 19, 28, 58 and 60 have been fully considered they are persuasive, therefore, the rejection is hereby withdrawn. However, upon further search and consideration Claims 1-36, 58, 60 and 102-140 are rejected in view of new ground of rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. **Claims 1-4, 5-9, 10-36, 58 and 102-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) in view of Alcamo (U.S. 3,123,077).**
7. Referring to **claims 1-3, 9 and 102-114**, Buncke discloses (see Figures 2 and 13) a barbed suture having a staggered disposition wherein the barb has an arcuate base (Fig. 13). Further, the barbs are all facing in a direction to the first and second end (see col. 9, lines 4-7). Buncke further discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns, the barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col. 8, lines 12-19). Buncke reference fails to disclose the barb cut angle ranging from about 140 degrees to about 175 degrees, however, what is abundantly clear from the Figure 15 of Buncke drawings is that the cutting blade has a sharp cutting edge, a base and an angle (see Figure below paragraph 5) whereby, said angle of the cutting blade creates the barb cut angle Θ on the suture (see Figure below paragraph 5). The Figure below paragraph 5 is a copy of Fig. 15 from Buncke

reference clearly shows the barb cut angle Θ , definitely, ranging from about greater than 0 degree to less than 180 degree, possibly, ranging from about 135 degree to less than 180 degree. Therefore, it would have been an obvious to a person of ordinary skill in art to derive the barb cut angle from the depth and spacings parameters given by Buncke, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention was made by the applicant to use have a barb cut angle ranging from about 140 degrees to about 175 degrees, because applicant has not disclosed that the umbrella structure shape provides an advantage, is used for a particular purpose, or solves a stated problem.

Still referring to **claims 1-3, 9 and 102-114**, Buncke disclose the invention substantially as claimed except for the barb further has an underside base that is arcuate. However, Alcamo discloses a suture includes barb members 2 and 2b, wherein barb members having curved edges (Figs. 3, 4 and col. 2, lines 1-5). It would have been obvious to one of ordinary skill in the art to modify the barb as disclosed by Buncke with the arcuate underside base as disclosed by Alcamo because it has been held that substitution of one known element for another to obtain predictable results is old and well known in the art. Further, due to lack of criticality in the specification about the underside base that is arcuate was shown to solve no particular problem, serve no particular purpose, and provide no

additional benefit as opposed to not having an underside arcuate base, one of ordinary skill in the art would expect the barb of Buncke/Alcamo perform equally well with applicant invention.

8. Referring to **claims 5-8**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col. 1, lines 20-25).
9. Referring to **claims 10-12 and 18**, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a direction to the first and second end (see col. 9, lines 4-7). Buncke further discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns, the barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col. 8, lines 12-19).
10. Referring to **claims 14-17**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col. 1, lines 20-25).
11. Referring to **claims 19-22 and 27**, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a direction to the first and second end (see col. 9, lines 4-7). Buncke further discloses the barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col. 8, lines 12-19). Buncke reference fails to disclose the barb cut

length and the ratio of the barb cut length to suture diameter ranging from about 0.2 to about 2. Here it is noted that Buncke disclose the spacings between barbs therefore the barb cut length is felt into this range. Furthermore, Buncke clearly discloses in Figure 15 the barb cut length is created by the cutting blade on wheel 90 (see Figure below paragraph 5). Definition of the word "ratio" according to the Merriam-Webster OnLine dictionary, is *the indicated quotient of two mathematical expressions or the relationship in quantity, amount, or size between two or more things*. Here it is noted that applicant fails to disclose the advantage or purpose of the ratio of barb cut length to the suture diameter. Buncke already discloses the suture diameter and the barb cut length and Buncke indicates that the depth of the barb depending, to a large extent, on the diameter of the suture material (see col. 8, lines 10-20), therefore, it would have been an obvious to a person of ordinary skill in art to describe the characteristic of the barb on the suture by using the ratio of barb cut length to the suture diameter involves only routine skill in the art.

12. Still referring to **claims 19-22 and 27**, it would have been an obvious to a person of ordinary skill in art to derive the ratio of the barb cut length to suture diameter ranging from about 0.2 to about 2 from the spacings and barb cut depth parameters given by Buncke, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention was made by the applicant to use have a ratio of the barb cut length

to suture diameter ranging from about 0.2 to about 2, because applicant has not disclosed that this ratio expression provides an advantage, is used for a particular purpose, or solves a stated problem.

Still referring to claims **19-22 and 27**, Buncke disclose the invention substantially as claimed except for the barb further has an underside base that is arcuate. However, Alcamo discloses a suture includes barb members 2 and 2b, wherein barb members having curved edges (Figs. 3, 4 and col. 2, lines 1-5). It would have been obvious to one of ordinary skill in the art to modify the barb as disclosed by Buncke with the arcuate underside base as disclosed by Alcamo because it has been held that substitution of one known element for another to obtain predictable results is old and well known in the art. Further, due to lack of criticality in the specification about the underside base that is arcuate was shown to solve no particular problem, serve no particular purpose, and provide no additional benefit as opposed to not having an underside arcuate base, one of ordinary skill in the art would expect the barb of Buncke/Alcamo perform equally well with applicant invention.

13. Referring to **claims 23-26**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col. 1, lines 20-25).
14. Referring to **claims 28-30 and 36**, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a

direction to the first and second end (see col. 9, lines 4-7). Buncke further discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns, the barb cut distance or barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col. 8, lines 12-19).

Still referring to **claims 28-30 and 36**, Buncke disclose the invention substantially as claimed except for the barb further has an underside base that is arcuate. However, Alcamo discloses a suture includes barb members 2 and 2b, wherein barb members having curved edges (Figs. 3, 4 and col. 2, lines 1-5). It would have been obvious to one of ordinary skill in the art to modify the barb as disclosed by Buncke with the arcuate underside base as disclosed by Alcamo because it has been held that substitution of one known element for another to obtain predictable results is old and well known in the art. Further, due to lack of criticality in the specification about the underside base that is arcuate was shown to solve no particular problem, serve no particular purpose, and provide no additional benefit as opposed to not having an underside arcuate base, one of ordinary skill in the art would expect the barb of Buncke/Alcamo perform equally well with applicant invention.

15. Referring to **claims 32-35**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col. 1, lines 20-25).

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16. Referring to **claim 58**, it is rejected for the same reason as claim 1 combined with the rejection of claims 10, 19, and 28.
17. Referring to **Claims 4, 13, 22, and 31**, Buncke/Alcamo discloses the invention substantially as claimed except for each set having a barb size different from the barb size of the other set. It would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to made one set of barb having a barb size different from the barb size of the other set because Applicant has not disclosed that this particular design provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Buncke/Alcamo, and applicant's invention, to perform equally well. Furthermore, A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Furthermore, it has been hold that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. Denied, 469 U.S. 830, 225 USPQ 232 (1984).
18. **Claims 115-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) and Alcamo (U.S. 3,123,077) as applied to claim 1 above and further in view of Ruff (U.S. 5,342,376).**

Buncke/Alcamo discloses the invention substantially as claimed except for the cross section of suture body has a non-circular cross section. Ruff discloses a barb suture having the cross section of suture body has a circular or non-circular cross section (see Figs. 7 and 9 and col. 6, lines 5-23). It has been held that substitution of one known element for another to obtain predictable results is old and well known in the art, therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to substitute the circular cross-section of the suture body as disclosed by Buncke/Alcamo with non-circular cross section. Further, Applicant has not disclosed that the suture body with a circular or non-circular cross section provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Ruff or Buncke/Alcamo, and applicant's invention, to perform equally well.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the

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reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claim 58 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 and 22 of copending Application No. 10/065280 (Pub. No. US 2004/0060410). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially claimed the same invention.
21. Claim 60 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 of copending Application No. 10/065280. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially claimed the same invention.
22. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **TUAN V. NGUYEN** whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
9/2/09